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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JUN SHI, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

AMPIO PHARMACEUTICALS, INC., MICHAEL MACALUSO, and THOMAS E. CHILCOTT,

Defendants.

Case No. 2:18-cv-07476-SJO-RAO

DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Hearing Date: June 1, 2020
Time: 10:00 a.m.
Courtroom: 10C

Judge: S. James Otero

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 1, 2020 at 10:00 a.m., or as soon thereafter as this matter can be heard before the Honorable S. James Otero, in Courtroom 10C of the First Street United States Courthouse, located at 350 West 1st Street, Los Angeles, California 90012, Defendants Ampio Pharmaceuticals, Inc., Michael Macaluso and Thomas E. Chilcott (collectively, "Defendants") will and hereby do move the Court for an order dismissing, with prejudice, all claims against Defendants in this action pursuant to the Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4, and Fed.R.Civ.P. 8(a), 9(b) and 12(b)(6). As stated more fully in the accompanying Memorandum of Points and Authorities, the claims asserted in the Amended Class Action Complaint should be dismissed because Plaintiffs have failed to state a claim upon which relief can be granted.

This Motion is based on this Notice of Motion and Motion, the attached Memorandum of Points and Authorities, the attached Declaration of Helen H. Yang and the exhibits thereto, Declaration of Sean L. McGrane and upon such oral argument and submissions that may be presented at or before the hearing on this Motion.

Pursuant to L.R. 7-3, this Motion is made following a conference of counsel. The parties were unable to reach a resolution regarding Defendants' stated grounds for dismissal, giving rise to this Motion.

Dated: Feb. 10, 2020

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By: */s/ Helen H. Yang*
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Sean L. McGrane
Helen H. Yang

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MEMORANDUM OF POINTS AND AUTHORITIES

In support of their motion to dismiss Plaintiffs' Amended Complaint, Ampio Pharmaceuticals, Inc. ("Ampio"), Michael Macaluso and Thomas E. Chilcott (collectively, "Defendants") submit the following:

I. PRELIMINARY STATEMENT

Ampio Pharmaceuticals, Inc. is working to develop and commercialize a product called "Ampion" to treat osteoarthritis of the knee—or "OAK"—which affects over 48 million people in the United States. Unlike many current treatments, Ampion is a non-opioid treatment for severe, chronic OAK.

Before a treatment like Ampion can be sold in the United States, it must be approved by the Food and Drug Administration (the "FDA"). The process for obtaining FDA approval is long and multi-faceted, and ultimately includes the filing of a Biologics License Application ("BLA") that must be approved by the FDA. A BLA may be filed only after the FDA reviews and accepts the results of multiple clinical trials showing the safety and efficacy of the new treatment.

In May 2017, after multiple meetings with the FDA, Ampio began conducting the AP-003-C clinical trial, which Ampio hoped would be its final clinical trial before submitting a BLA for Ampion. Ampio designed and conducted the trial in a manner that it believed was consistent with guidance it had received from the FDA in meetings held in the latter half of 2016 and early 2017. Ampio completed the AP-003-C trial in late 2017 and believed it to have successfully met its "primary endpoint." Ultimately, in July 2018, the FDA informed Ampio that it would not accept the results of the AP-003-C trial, which Ampio immediately disclosed to the market. Ampio's stock price fell, and this lawsuit for securities fraud followed.

Claims for securities fraud like those asserted here are subject to the heightened pleading standards of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), which was enacted by Congress to weed out the "practice of pleading fraud by hindsight." *DeMarco v. DepoTech Corp.*, 32 Fed. Appx. 260, 262

(9th Cir. 2002). To accomplish this end, the PSLRA requires securities fraud plaintiffs to plead with particularity facts showing that the defendants both made materially false or misleading statements and did so with the specific intent to defraud investors. In order to survive dismissal, the particularized factual allegations must support an inference of fraud that is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 309, 314 (2007).

Here, Plaintiffs rely on a theory that has been held to be implausible under the PSLRA: Plaintiffs claim that Defendants knew or were deliberately reckless in not knowing—prior to the commencement of the AP-003-C trial—that it was poorly designed and would be rejected by the FDA, but proceeded to spend considerable energy and resources to complete the trial anyway, and misled investors along the way. In the context of clinical trials, this precise theory has been rejected by courts in this District and elsewhere:

> Plaintiffs' entire Complaint rests on the notion that Defendant knew that ARC-520 has unsafe toxicity levels and hid that fact, deceiving the public in order [to] finance the testing of a drug it knew could never be approved by the FDA and thus never be brought to market. That scenario has been addressed by numerous authorities, finding it implausible.

In re: Arrowhead Pharms. Sec. Litig., No. CV 16-08505 PSG-PJW, 2017 U.S. Dist. LEXIS 217226, at *34-35 (C.D. Cal. Sept. 20, 2017); *see also In re Axonyx Sec. Litig.*, No. 05 Civ. 2307 (TPG), 2009 U.S. Dist. LEXIS 26029, at *8-9 (S.D.N.Y. March 27, 2009) ("The idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason . . . .").

Here, too, the theory should be rejected. The Amended Complaint contains no particularized facts—none—to support the requisite "compelling inference" of fraud. To the contrary, the more compelling and common sense nonfraudulent inference is that Defendants designed the AP-003-C trial with guidance from the FDA, believed

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it to have been successfully completed within the context of its design, and made disclosures accordingly. That the FDA ultimately declined to accept the study does not provide a hindsight basis to impose liability for securities fraud: "There is similarly no support for the theory that a company may be held liable for securities fraud for sponsoring a study that ultimately turns out to be flawed or poorly administered." *Anderson v. Peregrine Pharms., Inc.*, No. SACV-12-1647 PSG, 2013 U.S. Dist. LEXIS 120419, at *34 (C.D. Cal. Aug. 23, 2013).

II. PROCEDURAL & FACTUAL BACKGROUND[1]

A. The Parties to this Action

Ampio, a Delaware corporation headquartered near Denver, is a biopharmaceutical company primarily focused on the development of therapies to treat inflammatory conditions, including OAK. (Amnd. Compl. at ¶ 29.) Michael Macaluso is the Chief Executive Officer of Ampio and the Chairman of Ampio's Board of Directors, and has served in those roles throughout the putative class period. (*Id.* at ¶ 30.) Thomas E. Chilcott served as Ampio's Chief Financial Officer and Treasurer from August 16, 2017 through June 12, 2019. (*Id.* at ¶ 31.)

Lead Plaintiff George Nikolaou purports to be an Ampio shareholder and was appointed Lead Plaintiff by order of this Court dated September 27, 2019. (*Id.* at ¶27; ECF No. 67.) An individual named "Dean Geraci" also purports to be both an Ampio shareholder and a "named plaintiff" in this putative class action. (Amnd. Compl. at ¶ 28.)

[1] The facts herein are drawn from the Amended Complaint and are assumed as true for purposes of this Motion to Dismiss only. The facts herein are also drawn from the exhibits attached to the accompanying Declaration of Helen H. Yang ("Yang Decl."); each exhibit attached to the Yang Declaration is referenced in the Amended Complaint and thus may be considered on a motion to dismiss. *See Maloney v. Verizon Internet Servs.*, No. ED CV-08-1885-SGL(AGR), 2009 U.S. Dist. LEXIS 131027, at *7-8 (C.D. Cal. Oct. 4, 2009) ("[A] court may take documents into account that are referenced in the complaint but are not attached to it when considering whether to dismiss.") (citing *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir. 1998)).

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B. The Development of Ampion and the AP-003-C Clinical Trial.

Since at least 2011, Ampio has been working to develop and commercialize Ampion. (*Id.* at ¶ 44.) Unlike most current treatment options for patients suffering from severe, chronic OAK, Ampion is a non-opioid injectable treatment. (*Id.* at ¶¶ 48-49.)

In support of its efforts to submit a BLA to the FDA, Ampio has conducted a number of clinical trials testing the safety and efficacy of Ampion. In 2013, Ampio successfully completed its "SPRING" trial and submitted its results to the FDA. (*Id.* at ¶¶ 59-60.) In or around December 2013, the FDA informed Ampio that the SPRING trial qualified as a "Phase III trial" necessary to support a BLA; the FDA also recommended that Ampio conduct a second Phase III trial prior to submitting its BLA. (*Id.* at ¶ 60.)

Per this recommendation, Ampio conducted two separate Phase III clinical trials for Ampion between 2014 and 2016, but neither was successful. (*Id.* at ¶¶ 62-70.) Following the second unsuccessful trial, Ampio representatives met with the FDA's Center for Biologics Evaluation and Research Division in September and December 2016 to seek guidance on the best path forward. (*Id.* at ¶ 88.) Discussions with the FDA continued into the early part of 2017. (*Id.*)

Based on these discussions with the FDA, Ampio designed and eventually commenced the AP-003-C clinical trial. (*Id.* at ¶ 75.) Ampio designed the trial to include 171 patients. (*Id.*) Approximately 85% of the patients were to be treated with Ampion, while the remaining 15% were to be treated with a placebo, saline. (*Id.*) The trial was designed so that the results of the patients treated with Ampion would be compared against the results of patients treated with placebos in Ampion's prior clinical trials. (*Id.*)

On May 1, 2017, Ampio announced to the public that it had commenced the AP-003-C trial. (*Id.*) Between May 1, 2017 and August 7, 2018, Ampio made a number of public disclosures regarding the clinical trial, five of which are the subject

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of the Amended Complaint.

1. May 1, 2017: Ampio announced in a press release that it had commenced the AP-003-C trial and that, "in compliance with FDA guidance, this trial will be smaller than our prior trials . . . ." The press release provided additional details on the design, methodology and "primary endpoint" of the AP-003-C trial. (Yang Decl., Ex. A.)
2. June 22, 2017: Ampio announced in a press release that it had injected its first patient in the AP-003-C trial. (*Id.*, Ex. B.)
3. December 14, 2017: Ampio announced in a press release that the AP-003-C trial had successfully met its "primary endpoint," and that the results of the trial "exceed[ed] the physician reported threshold of 30% for a meaningful treatment" of patients with severe OAK. (*Id.*, Ex. C at p. 1.)
4. January 2018: In a PowerPoint presentation compiled by management, Ampio stated that it "successfully completed" the AP-003-C trial. (*Id.*, Ex. D at p. 3.)
5. March 6, 2018: In its 2017 annual report filed with the Securities and Exchange Commission ("SEC"), Ampio stated that it had "successfully completed" the AP-003-C trial. (*Id.*, Ex. E. at p. 3.)

Ultimately, while Ampio believed that the AP-003-C trial successfully met its primary endpoint, the FDA wrote to Ampio in July 2018 and stated that the AP-003-C trial did not provide sufficient evidence of effectiveness to support a BLA. (Amnd. Compl. at ¶¶ 104-05.) Ampio promptly disclosed this development to the market: "Despite our belief that the AP-003-C trial design was based on FDA guidance and feedback . . . the FDA does not consider the AP-003-C trial to be an adequate and well-controlled clinical trial." (*Id.* at ¶ 104.) Ampio further disclosed that the FDA had "recommended that we perform an additional randomized trial" in support of a BLA for Ampion. (*Id.*)

Although Ampio disagreed with the FDA's decision, Ampio continued working with the FDA on another Phase III trial. (*Id.* at ¶¶ 104, 113.) On June 14,

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2019, Ampio announced that it had begun a new clinical trial, which was in progress as of the date of the filing of the Amended Complaint. (*Id.* at ¶¶ 113-114.)

III. COUNT ONE SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM

A. The PSLRA Imposes Heightened Pleading Standards on Plaintiffs.

Count I of the Amended Complaint is for securities fraud under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), and SEC Rule 10b-5 promulgated thereunder. "To plead a claim under Section 10(b), and Rule 10b-5, a plaintiff must allege (1) a material misrepresentation or omission (falsity); (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Paddock v. Dreamworks Animation SKG, Inc.*, No. CV 14-06053 SJO, 2015 U.S. Dist. LEXIS 188956, at *5 (C.D. Cal. Apr. 1, 2015) (Otero, J.).

As this Court and the Ninth Circuit have recognized, "plaintiffs in private securities fraud class actions face formidable pleading requirements" to avoid dismissal. *Id.* at *5-6 (citations omitted). Specifically, securities fraud plaintiffs must plead particularized factual allegations to support the first two elements of their claim, falsity and scienter. *Anderson*, 2013 U.S. Dist. LEXIS 120419, at *17. "If either of these elements has not been sufficiently pled, the court shall, on motion of any defendant, dismiss the complaint." *Kairalla v. Advanced Med. Optics, Inc.*, No. CV 07-05569 SJO (PLA), 2008 U.S. Dist. LEXIS 76897, at *7 (C.D. Cal. June 6, 2008) (quoting 15 U.S.C. § 78u-4(b)(3)(A)).[2]

[2] The Ninth Circuit has noted that "falsity and scienter [] are generally strongly inferred from the same set of facts, and the two requirements may be combined into a unitary inquiry under the PSLRA." *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1091 (9th Cir. 2002) (internal quotations omitted). While Defendants address both falsity and scienter in this Motion, the Court may dismiss Plaintiffs' claims on either or both grounds, and may consider scienter prior to falsity. *See, e.g., Nguyen v. Endologix, Inc.*, No. 17-00017-AB (PLA), 2018 U.S. Dist. LEXIS 233252, at *13-14 (C.D. Cal. Sept. 6, 2018) ("Here, the Court finds it appropriate to focus on whether the relevant allegations give rise to a strong inference of scienter, and to address falsity as necessary within that analysis.").

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B. Plaintiffs Fail To Plead Falsity with Particularity.

To state a claim, Plaintiffs must first plead particularized facts showing falsity—that is, a material misrepresentation or an omission of material fact. *In re Rigel Pharmaceuticals, Inc. Secs. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). Plaintiffs must "state with particularity each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and all facts on which that belief is formed." *Paddock*, 2015 U.S. Dist. LEXIS 188956, at *7.

Plaintiffs purport to identify five materially false or misleading statements, which can be grouped into two categories: (i) statements at or near the start of the AP-003-C clinical trial (in May 2017 and June 2017), relating to the design and methodology of the trial (the "Design Statements"); and (ii) statements following the conclusion of the trial (in December 2017, January 2018 and March 2018), in which Ampio described positively the results of the AP-003-C clinical trial (the "Results Statements"). Plaintiffs have failed to plead particularized facts showing the falsity of any of these statements.

1. The Design Statements

On May 1, 2017, Ampio issued a press release announcing that it had initiated the AP-003-C clinical trial. (Yang Decl., Ex. A.) The press release provided details regarding the trial's design and methodology and disclosed that the trial's "primary endpoint"—its benchmark for success—would follow the "Osteoarthritis Research Society International (OARSI) guidance, utilizing the Outcome Measures in Rheumatology Clinical Trials (OMERACT) OMERACT-OARSI responder rate." (*Id.*) Approximately seven weeks later, on June 22, 2017, Ampio issued another press release stating it had injected its first patient in the trial. (Yang Decl., Ex. B.)

Plaintiffs excerpt portions of each press release but fail to specifically identify which statements are alleged to have been false or misleading and why, as they are required to do under the PSLRA. *See* 15 U.S.C. § 78u-4 ("[T]he complaint shall specify each statement alleged to have been misleading [and] the reason or reasons

why the statement is misleading . . . .") (emphasis added); *see also In re Harmonic Inc. Secs. Litig.*, 163 F. Supp. 2d 1079, 1097 (N.D. Cal. 2001) (dismissing securities fraud claims where plaintiff failed to "specify the statements alleged to be misleading"). For this reason alone, Plaintiffs fail to adequately plead falsity.

Moreover, Plaintiffs do not allege that Ampio's description of the trial's design and methodology in the May 1 press release was false or misleading, or that its description of the study's "primary endpoint" was false or misleading. To the contrary: It is undisputed that Ampio conducted the trial precisely as it said it would in these press releases, and did not misstate the trial's design, methodology and primary endpoint.

In the absence of any objectively false or misleading statements, Plaintiffs attempt to manufacture a securities fraud violation by ignoring and twisting the language of the press releases. Plaintiffs allege that the press releases were "false and/or misleading" because, *inter alia*, "AP-003-C's design was not formally or informally approved by the FDA." (Amnd. Compl. at ¶¶ 76, 79.) But Ampio never said, in either release, that the FDA had "formally or informally approved" the trial's design. (*See* Yang Decl., Exs. A & B.) The June 22 press release does not mention the FDA at all. (*Id.*, Ex. B.) And the May 1 press release only states that Ampio had designed certain aspects of the trial in compliance with "FDA guidance." (*Id.*, Ex. A. at p. 1.) This is in fact true: "[T]he FDA provided input" to Ampio in advance of the commencement of the AP-003-C trial, as Plaintiffs acknowledge. (Amnd. Compl. at ¶ 89.) Ampio's undisputedly accurate disclosure—that it had received guidance from the FDA—does not equate to a statement Ampio never made—that the FDA had "approved" the trial's design.

Plaintiffs also allege that that the press releases were false or misleading because "Defendants knew or should have known that the AP-003-C was not designed to be an adequate or well-controlled study because of its low participation and lack of a concurrent control group." (Amnd. Compl. at ¶ 76, 79.) As discussed

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further below, however, Plaintiffs do not plead any particularized facts to support this implausible, conclusory allegation, or to show that Defendants did not actually believe that the trial was adequately designed. *Infra* at pp. 12-16.

2. The Results Statements

In a December 2017 press release (Yang Decl., Ex. C), a January 2018 PowerPoint presentation (*Id.*, Ex. D), and a March 2018 filing with the SEC (*Id.*, Ex. E), Ampio reported positive results for the AP-003-C trial. In the December 2017 press release, Ampio stated that "the Phase 3 clinical trial of Ampion met its primary endpoint with 71% of Ampion treated patients meeting the OMERACT-OARSI responder criteria, which exceeds the physician reported threshold of 30% . . . ." (*Id.*, Ex. C at p. 1.) In the January 2018 PowerPoint, Ampio stated that it had "successfully completed" the AP-003-C trial, noting later that the trial had "met [its] primary endpoint with 71% of patients meeting OMERACT-OARSI responder criteria." (*Id.*, Ex. D at pp. 2, 12.) Ampio made the same statements in the March 2018 filing with the SEC. (*Id.*, Ex. E at pp. 6, 38.)

As with the Design Statements, Plaintiffs excerpt portions of each document but do not identify which specific statements within these three documents are alleged to have been false or misleading or why. Plaintiffs thus failed to satisfy their heightened burden to plead falsity with particularity under the PSLRA. *Supra* at p.8.

Moreover, again, Plaintiffs do not identify any objectively false or misleading statements within the Results Statements. They do not dispute that the AP-003-C trial actually did meet its primary endpoint, as designed, or that 71% of Ampion treated patients met the OMERACT-OARSI responder criteria. Undisputedly, these disclosures were and are objectively accurate: Within the context of its disclosed design, the AP-003-C trial was successful, and the Results Statements are thus not actionable under the federal securities laws. *See, e.g., Micholle v. Ophthotech Corp.*, No. 17-CV-210 (VSB), 2019 U.S. Dist. LEXIS 160131, at *28 (S.D.N.Y. Sept. 18, 2019) (finding that complaint failed "to satisfactorily allege that [d]efendants'

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statements regarding the success of the Phase 2b Trial were materially misleading," where defendants accurately disclosed design and methodology of trial).

As with the Design Statements, Plaintiffs attempt to manufacture a misstatement by conflating two separate concepts—(i) whether Ampio had "successfully completed" the AP-003-C trial within its disclosed design, and (ii) whether the FDA would ultimately accept the design and the results of the trial. Ampio never stated in any of the Results Statements (or elsewhere) that the FDA had approved the design of the trial or had accepted the results of the trial, and never told investors that FDA approval was assured. Again, Plaintiffs cannot manufacture falsity by misstating Ampio's actual disclosures. *See, e.g., Nobel Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04-cv-1030-RPM, 2005 U.S. Dist. LEXIS 24452, at *29 (D. Colo. Oct. 20, 2005) (dismissing claims for failure to plead falsity where pharmaceutical company reported positive results but "did not tell investors that FDA approval was assured").

C. Plaintiffs Fail to Plead Scienter with Particularity.

"Scienter is defined as a mental state embracing intent to deceive, manipulate or defraud." *Paddock*, 2015 U.S. Dist. LEXIS 188956, at *8 (internal quotations omitted). As the United States Supreme Court has held, in order to survive dismissal, the plaintiff must do more than simply "allege sufficient facts to support a plausible claim for relief," as would be enough outside the securities fraud setting. *In re Arrowhead*, 2017 U.S. Dist. LEXIS 217226, at *6 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).[3] Rather, the plaintiff must plead particularized facts giving rise to a strong "inference of scienter" that is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. Claims for securities fraud should

[3] A claim that is implausible under *Twombly* can be dismissed without even engaging in the comparative cogency analysis required under the PSLRA. *See, e.g., Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989-92 (9th Cir. 2009).

be dismissed where "the inference that the defendants intended to deceive investors is less compelling than a competing inference of non-fraudulent intent." *Sharenow v. Impac Mortg. Holdings, Inc.*, 385 Fed. Appx. 714, 716-17 (9th Cir. 2010).

As with falsity, Plaintiffs must plead scienter with particularity for each and every alleged misstatement of fact. 15 U.S.C. §§ 78u-4 ("[T]he complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."). Courts are to scrutinize a complaint's scienter allegations both individually and holistically in order "to determine whether, taken together, the allegations create a strong inference of scienter." *In re Alphabet, Inc. Sec. Litig.*, Case No. 18-cv-06245-JSW, ECF No. 82 at p. 7 (N.D. Cal. Feb. 5, 2020).

In the Ninth Circuit, in order to adequately plead scienter, "the complaint must state with particularity facts giving rise to a strong inference that the defendant made false or misleading statements either intentionally or with deliberate recklessness." *Paddock*, 2015 U.S. Dist. LEXIS 188956, at *8 (emphasis added). "Deliberate recklessness" is a more culpable state of mind than negligence or simple recklessness—it is a state of mind that, as this Court has held, "reflects some degree of intentional or conscious misconduct" and shows an "extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id.* at *8. "The recklessness inquiry turns on what the defendant actually believed and the information to which he actually had access at the time he made the statements alleged to be false, as [h]onest optimism followed by disappointment is not the same as lying or misleading with deliberate recklessness." *Anderson*, 2013 U.S. Dist. LEXIS 120419, at *21-22.

While the failure to plead falsity alone dooms the ability to plead scienter, *see In re Vantive Corp. Sec. Litig.*, 283 F.3d at 1091, here Plaintiffs also fail to plead particularized, non-conclusory, factual allegations to show that the Defendants knew,

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or were deliberately reckless in not knowing, that their supposedly false or misleading statements were so when made.

1. There are no allegations that Defendants had contemporaneous information showing that their statements were false or misleading.

"Courts addressing scienter in the context of statements regarding clinical trials of pharmaceutical products have focused on whether the defendants alleged to have made misleading statements had access to or actual knowledge of information contradicting the veracity of their statements when the statements were made." *In re: Arrowhead*, 2017 U.S. Dist. LEXIS 217226, at *35-36; *see also In re Rigel Pharms., Inc. Secs. Litig.*, 697 F.3d 869 (9th Cir. 2012) (affirming dismissal of securities fraud claims based on Defendants' statements regarding efficacy and safety of clinical trial). Claims should be dismissed for failure to plead scienter where the complaint lacks particularized facts showing that Defendants had access to, or actual knowledge of, contemporaneous information that rendered their statements false or misleading when made. *In re Arrowhead*, 2017 U.S. Dist. LEXIS 217227, at *33; *see also In re Resonant Sec. Litig.*, No. CV 15-01970 SJO, 2016 U.S. Dist. LEXIS 61454, at *18 (C.D. Cal. Feb. 8, 2016) (Otero, J.) ("Plaintiffs do not point to contemporaneous information, known to Defendants at the time they made public filings or statements, that demonstrates that Defendants knew that producing Skyworks Duplexer was impossible.").

Here, there are no particularized factual allegations—none—to show that any of the Defendants knew or had access to contemporaneous information that contradicted their public statements regarding the design, progress and results of the AP-003-C trial. There are no particularized allegations of specific reports sent to, or written or oral communications with, Defendants that contradicted their statements regarding the clinical trial. That includes any communications with the FDA during the putative Class Period contradicting what Defendants stated about the Ampion trial's design, progress and results. Plaintiffs have not pleaded (and cannot plead)

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scienter.

This Court's opinion in *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1126 (C.D. Cal. Sept. 19, 2005), is persuasive on this point. In *Yanek*, plaintiffs brought securities fraud claims against the manufacturer of eye care products, alleging that the defendants had failed to disclose "FDA compliance problems." *Id.* at 1124-25. This Court, however, declined to find scienter for the first part of the putative class period—the "Early Class Period"—because plaintiffs had failed to plead particularized facts showing that defendants had contemporaneous information suggesting the FDA would not approve the subject product: "Plaintiffs do not allege any facts showing that . . . FDA compliance problems existed, Defendants actually knew of these problems, or that these problems would preclude FDA approval of the ICL. These Early Class Period allegations fail to plead scienter with particularity." *Id.* at 1126. And—unlike the "Later Class Period" in *Yanek*, where the Court did find scienter had been pleaded—the Amended Complaint here contains no particularized factual allegations showing that (i) the FDA ever communicated to Defendants, prior to August 2018, that the AP-003-C trial would not be acceptable; or (ii) Defendants had any other contemporaneous information suggesting that the AP-003-C trial was poorly designed and destined to fail. Moreover, Ampio promptly disclosed the FDA's rejection of the trial, unlike the defendants in *Yanek*, who failed to disclose the FDA's objections.

Defendants never stated or implied that the FDA had approved or pre-approved the AP-003-C trial, and Plaintiffs do not and cannot allege particularized facts showing otherwise. That the FDA ultimately declined the trial results does not support a hindsight inference that the Defendants intended to defraud the market, and courts in this District have expressly rejected such an inference in the context of clinical trials: "[I]n cases in which the allegations support an inference that the defendant had a good faith belief in the truth of the statements regarding the drug's efficacy when the statements were made and did not have access to contrary

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information, courts have found that scienter is not adequately alleged." *Anderson*, 2013 U.S. Dist. LEXIS 120419, at *26-27. The same rationale applies here: There are no well-pleaded factual allegations to show that Defendants did not believe that the AP-003-C trial had been designed in compliance with FDA guidance and had been successfully completed within the context of that guidance. The absence of such allegations defeats any inference of scienter.

2. Allegations attributed to "Confidential Witnesses" do not support a compelling inference of scienter.

Plaintiffs attempt to cobble together an inference of scienter by relying upon allegations attributed to three so-called "confidential witnesses." (Amnd. Compl. at ¶¶ 58, 90-92, 108-09.) In the Ninth Circuit, a securities fraud plaintiff may rely on information purportedly supplied by confidential witnesses "so long as the sources are described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Kairalla*, 2008 U.S. Dist. LEXIS 76897, at *21-22. However, even assuming the source is described with sufficient particularity, allegations attributed to the source can be rejected where they "fail[] to support an inference of scienter." *Id.*

"Confidential Witness 1" ("CW 1") is described as the former Chief Regulatory Affairs Officer at Ampio. (Amnd. Compl. at ¶ 58.) He is alleged to have left Ampio in "mid-2016"—before Ampio met with the FDA in September and December 2016, and nearly one year before Defendants are alleged to have begun making the allegedly false or misleading statements in May 2017. (*Id.*) Indeed, Plaintiffs acknowledge that CW 1 "did not participate in the design of AP-003-C." (*Id.* at ¶ 90.) Thus, CW 1 has no personal knowledge as to (i) discussions with the FDA preceding the AP-003-C trial and/or (ii) Defendants' state of mind when they made statements regarding the clinical trial's design, progress and results. Allegations attributed to CW 1 should accordingly be disregarded. *See, e.g., Kairalla*, 2008 U.S. Dist. LEXIS 76897, at *25 (rejecting allegations attributed to confidential

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witness because they bore "no relevance . . . to a determination that [defendants] acted with scienter").

Moreover, CW 1 offers only hindsight criticisms of the AP-003-C trial's methodologies. (*Id.* at ¶¶ 58, 90.) Even if these hindsight criticisms were valid, there are no particularized allegations that any defendant had such knowledge contemporaneous with the making of the alleged misstatements, including by reason of a communication from CW 1. Absent such allegations, the remaining allegations do not support a finding of scienter. *See, e.g.*, No. 10 C 6826, *City of New Orleans Emples. Ret. Sys. v. Private Bancorp, Inc.*, 2011 U.S. Dist. LEXIS 128352, at *18 (N.D. Ill. Nov. 3, 2011) (dismissing securities fraud claim where confidential witness was not alleged to have communicated information directly to defendants).

The allegations attributed to "Confidential Witness 2" ("CW 2") are even weaker. CW 2 is alleged to have stated that it is "'really hard' . . . to guarantee that the FDA would endorse" the design of a clinical trial, and to have wondered why "Ampio did not obtain" a Special Protocol Assessment ("SPA") in advance of the AP-003-C trial. (Amnd. Compl. at ¶ 92.) (As alleged in the Amended Complaint, an SPA is an agreement with the FDA in advance of a clinical trial that "can significantly de-risk the path to market." (Amnd. Compl. at ¶¶ 66-67.)) These allegations, however, are strawmen: Defendants never "guaranteed" that the FDA would endorse the AP-003-C trial, and never stated that Ampio had obtained an SPA in advance of the trial. Nor does, or could, CW 2 allege that SPAs must be obtained, as they are mere alternative processes, as Plaintiffs acknowledge in the Amended Complaint. (*Id.*) CW 2's allegations thus say nothing about whether the Defendants knew, or were deliberately reckless in not knowing, that their statements were false or misleading when made, and CW 2's allegations should be given no weight in the scienter analysis.

Finally, the only allegation attributed to "Confidential Witness 3" ("CW 3") is that he attended a meeting held by Defendant Macaluso "to inform employees of the

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FDA's decision" to reject the trial, at which meeting Defendant Macaluso is alleged to have stated that "the number of participants in AP-003-C was too few." (*Id.* at ¶¶ 108-09.) This meeting was allegedly held in July or August of 2018—four months after the last alleged misstatement. (*Id.*) The allegation has no bearing on what Defendants knew, or were deliberately reckless in not knowing, at the time they made the purported misstatements. To the contrary—the allegation actually supports the nonfraudulent inference that Defendants were surprised by the FDA's decision.

3. Boilerplate allegations regarding normal business prospects fail to support a compelling inference of scienter.

Plaintiffs also attempt to plead scienter by relying upon boilerplate allegations that Ampio was motivated to deceive the market about the AP-003-C trial in order to attract investors or merger partners. (Amnd. Compl. at ¶¶ 74, 118.) These boilerplate scienter allegations regarding a company's desire to improve its financial outlook have repeatedly been rejected by this Court and others as insufficient to show a cogent inference of scienter: "[I]f scienter could be pleaded merely by alleging that officers and directors possess such motive and opportunity to enhance a company's business prospects, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." *Yanek*, 388 F. Supp. 2d at 1128-29 (internal quotations omitted); *see also Anderson*, 2013 U.S. Dist. LEXIS 120419, at *39.

These boilerplate allegations are even less compelling where, as here, Ampio was forthright throughout the putative Class Period as to its financial position and that it needed to (and did) raise additional capital in order to complete the AP-003-C trial and bring Ampion to market. (*See, e.g.*, Amnd. Compl. at ¶¶ 72-75.) Courts have declined to infer scienter in similar circumstances, noting the lack of any "hidden agenda" to deceive the market. *See In re Axonyx*, 2009 U.S. Dist. LEXIS 26029, at *11 ("[T]he allegations in the complaint here indicate that Axonyx was, as it said, embarking on the Phase III trial, and seeking financing for its continuing

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efforts to develop Phenserine as a marketable product. No real basis is pleaded for a 'hidden agenda' claim.").

4. There are no allegations of insider trading to support a compelling inference of scienter.

Plaintiffs also fail to plead any "unusual or suspicious" insider stock sales that would give rise to a compelling inference of scienter. While Plaintiffs allege a subpoena was received by Ampio in connection with an insider trading investigation, (Amnd. Compl. at ¶ 119), Plaintiffs fail to allege a single trade by any Defendant that was unusual or suspicious, and thus fail to adequately plead scienter. *See Zucco*, 552 F.3d at 1005-06 (holding that a plaintiff must, at a minimum, provide each defendant's "meaningful trading history," so that a court may gauge whether the sales are "unusual or suspicious" so as to support an inference of scienter); *see also Yanek*, 388 F. Supp. 2d at 1128 (no scienter where complaint failed to allege that specific stock sales by defendants were suspicious or unusual in timing or amount).

5. The more compelling, nonfraudulent inference is that Ampio believed the AP-003-C clinical trial was properly designed and successfully met its endpoint.

Finally, with the benefit of hindsight, Plaintiffs criticize the design and methodology of the AP-003-C trial, and suggest that the Defendants knew, or were deliberately reckless in not knowing, that the trial design was flawed. *See, e.g.*, Amnd. Compl. at ¶¶ 86-87 (criticizing trial for being too small and not using a concurrent control group); *id.* at ¶ 58 (criticizing use of saline as a placebo). But in support of these hindsight criticisms, Plaintiffs rely entirely on (i) the musings of CW 1, who left Ampio before the commencement of the AP-003-C trial and was not involved in its design; and (ii) a 1998 study from the FDA that suggests the "use of historical control studies" is reserved for "special circumstances." (*Id.* at ¶¶ 58, 87). Neither supports a compelling inference that the Defendants knew, or were deliberately reckless in not knowing, that their statements regarding the design, progress and results of the AP-003-C trial were false or misleading at the time they were made.

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As courts have held, this hindsight quibbling with the design and results of a clinical trial is insufficient to plead scienter. *See Anderson*, 2013 U.S. Dist. LEXIS 120419, at *34.

Indeed, the entire premise of Plaintiffs' claims—that Defendants knowingly or with deliberate recklessness conducted a defective trial—is implausible. This precise theory has been considered and rejected by numerous courts across the country:

- "The allegation of securities fraud here is premised on plaintiffs' belief that defendants did not design the first Phase III trial properly. . . . [T]hey claim that defendants knew or recklessly ignored the fact that the clinical trial was defective, and that any statements about the trial's progress were therefore necessarily misleading. **But it must be said that the chances of this kind of thing actually occurring are surely remote. The idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason . . . .**" *In re Axonyx Sec. Litig.*, 2009 U.S. Dist. LEXIS 26029 at *8-9;
- "Plaintiffs' entire Complaint rests on the notion that Defendant knew that ARC-520 has unsafe toxicity levels and hid that fact, deceiving the public in order to finance the testing of a drug it knew could never be approved by the FDA and thus never be brought to market. That scenario has been addressed by numerous authorities, finding it implausible." *Arrowhead*, 2017 U.S. Dist. LEXIS 217226, at *34-35;
- "The notion that BMTI would recklessly forego necessary tests and studies or hide adverse events makes little sense . . . . Plaintiffs' own allegation is that Augment is BMTI's flagship product and necessary to the company's success, begging the question why it would sabotage all of the company's efforts up to that point." *Sarafin v. BioMimetic Therapeutics, Inc.*, No. 3:11-0653, 2013 U.S. Dist. LEXIS 4909, at *47 (M.D. Tenn. Jan. 10, 2013).

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This Court should likewise reject Plaintiffs' theory and adopt the Amended Complaint's more compelling, nonfraudulent inference—that Defendants designed the AP-003-C trial with guidance from the FDA and conducted the trial with the good faith belief that it would be accepted by the FDA, and made disclosures accordingly.

Examining the allegations of the Amended Complaint both individually and holistically, Plaintiffs have failed to plead scienter with the particularity required by the PSLRA. Accordingly, Count I should be dismissed.[4]

IV. PLAINTIFFS' SECTION 20 CLAIM (COUNT II) ALSO FAILS

"In order to prove a prima facie case under Section 20(a), a plaintiff must prove: (1) a primary violation of federal securities law; and (2) that the defendant exercised actual power or control over the primary violator." *Paddock*, 2015 U.S. Dist. LEXIS 188956, at *4-5. "Section 20(a) claims may be dismissed summarily . . . if a plaintiff fails to adequately plead a primary violation of Section 10(b)." *Id.* Here, since Plaintiffs have failed to adequately plead a primary violation of Section 10(b), their claim for violations of Section 20(a) (Count Two) should also be dismissed.

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[4] Plaintiffs also rely on an article published on the *Seeking Alpha* website in an attempt to show scienter. The article is not attached to the Amended Complaint, but the excerpted portion conclusorily suggests that Ampio intentionally "conduct[ed] a trial that nearly guaranteed success." (AC at ¶ 117.) Neither the article nor the Amended Complaint states facts in support of this allegation, besides a vague reference to a "confidential management presentation." (*Id.*) These vague, non-particularized allegations do not show scienter under the PSLRA.

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V. CONCLUSION

Defendants respectfully request that this Court enter an order dismissing the claims asserted in the Amended Complaint, in their entirety and with prejudice.[5]

Dated: Feb. 10, 2020

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[5] Plaintiffs have already had one opportunity to amend their complaint and should not be granted leave to amend again: "[W]here the plaintiff has previously been granted leave to amend and has subsequently failed to add the requisite particularity to its claims, the district court's discretion to deny leave to amend is particularly broad." *Zucco*, 552 F.3d 981, 1007 (9th Cir. 2009).